

WHAT IS CLAIMED IS:

1. A method for detecting an analyte residing in a test sample, said method comprising:

5 i) providing a flow-through assay device comprising a porous membrane that is in fluid communication with detection probes conjugated with a specific binding member for the analyte, wherein the assay device defines a scavenging zone and a detection zone, each of said zones containing a capture reagent for the analyte;

10 ii) contacting said scavenging zone with the test sample so that a quantity of the analyte less than or equal to a predefined base quantity binds to said capture reagent at said scavenging zone;

iii) contacting said conjugated detection probes with the test sample; and

15 iv) allowing the test sample and said conjugated detection probes to flow to said detection zone so that said conjugated detection probes or complexes thereof bind to said capture reagent and generate a detection signal, wherein the quantity of analyte in the test sample in excess of said predefined base quantity is proportional to the intensity of said detection signal.

20 2. A method as defined in claim 1, wherein said capture reagent at said scavenging zone is selected from the group consisting of antigens, haptens, protein A or G, neutravidin, avidin, streptavidin, captavidin, antibodies, and complexes thereof.

3. A method as defined in claim 1, wherein said capture reagent at said scavenging zone includes an antibody.

4. A method as defined in claim 3, wherein the analyte includes an antigen.

25 5. A method as defined in claim 1, wherein said capture reagent at said detection zone is selected from the group consisting of antigens, haptens, protein A or G, neutravidin, avidin, streptavidin, captavidin, antibodies, and complexes thereof.

30 6. A method as defined in claim 1, wherein said capture reagents at said scavenging zone and said detection zone are substantially identical.

7. A method as defined in claim 1, wherein the test sample contacts said conjugated detection probes only after contacting said scavenging zone.

8. A method as defined in claim 1, wherein said assay device comprises a

sampling pad that defines said scavenging zone.

9. A method as defined in claim 8, wherein said assay device further comprises a conjugate pad located downstream from said sampling pad, wherein said conjugated detection probes are applied to said conjugate pad.

5 10. A method as defined in claim 1, wherein said assay device further defines a calibration zone within which a capture reagent is immobilized that is configured to bind to said detection probes or calibration probes, said calibration zone generating a calibration signal.

10 11. A method as defined in claim 10, further comprising comparing the intensity of the detection signal to the intensity of the calibration signal, wherein the quantity of the analyte within the test sample in excess of said predefined base quantity is proportional to the intensity of the detection signal calibrated by the intensity of the calibration signal.

15 12. A method as defined in claim 1, wherein said detection probes comprise a substance selected from the group consisting of chromogens, catalysts, luminescent compounds, radioactive compounds, direct visual labels, liposomes, and combinations thereof.

13. A method as defined in claim 1, wherein said capture reagent is immobilized within said scavenging zone.

20 14. A method as defined in claim 1, wherein said detection zone is located downstream from said scavenging zone.

15. A method for detecting an antigen residing in a test sample, said method comprising:

25 i) providing a flow-through assay device comprising a porous membrane that is in fluid communication with detection probes conjugated with a specific binding member for the antigen, wherein the assay device defines a scavenging zone and a detection zone located downstream from said scavenging zone, each of said zones containing a capture reagent capable of specifically binding to the antigen, wherein said capture reagent of said scavenging zone includes an
30 antibody;

ii) contacting said scavenging zone with the test sample so that a quantity of the antigen less than or equal to a predefined base quantity binds to said antibody at said scavenging zone;

iii) thereafter, contacting said conjugated detection probes with the test sample; and

iv) allowing the test sample and said conjugated detection probes to bind to said capture reagent at said detection zone and generate a detection signal, wherein the quantity of antigen in the test sample in excess of said predefined base quantity is proportional to the intensity of said detection signal.

16. A method as defined in claim 15, wherein the antigen includes C-reactive protein.

17. A method as defined in claim 15, wherein said capture reagent at said detection zone includes an antibody.

18. A method as defined in claim 15, wherein said capture reagents at said scavenging zone and said detection zone are substantially identical.

19. A method as defined in claim 15, wherein said assay device further defines a calibration zone within which a capture reagent is immobilized that is configured to bind to said detection probes or calibration probes, said calibration zone generating a calibration signal.

20. A method as defined in claim 19, further comprising comparing the intensity of the detection signal to the intensity of the calibration signal, wherein the quantity of the analyte within the test sample in excess of said predefined base quantity is proportional to the intensity of the detection signal calibrated by the intensity of the calibration signal.

21. A method as defined in claim 15, wherein said detection probes comprise a substance selected from the group consisting of chromogens, catalysts, luminescent compounds, radioactive compounds, direct visual labels, liposomes, and combinations thereof.

22. A method as defined in claim 15, wherein said antibody is immobilized within said scavenging zone.

23. A flow-through assay device for detecting an analyte residing in a test sample, said assay device comprising a porous membrane that is in fluid communication with detection probes conjugated with a specific binding member for the analyte, said assay device defining:

a scavenging zone that contains a capture reagent configured to bind to a quantity of the analyte less than or equal to a predefined base quantity; and

a detection zone within which a capture reagent is immobilized that is configured to bind to said conjugated detection probes or complexes of said conjugated detection probes and any analyte that does not bind to said scavenging zone, wherein said detection zone is configured to generate a detection signal so that the quantity of analyte in the test sample in excess of said predefined base quantity is proportional to the intensity of the detection signal.

24. An assay device as defined in claim 23, wherein said capture reagent at said scavenging zone is selected from the group consisting of antigens, haptens, protein A or G, neutravidin, avidin, streptavidin, captavidin, antibodies, and complexes thereof.

25. An assay device as defined in claim 23, wherein said capture reagent at said scavenging zone includes an antibody.

26. An assay device as defined in claim 25, wherein the analyte includes an antigen.

27. An assay device as defined in claim 23, wherein said capture reagent at said detection zone is selected from the group consisting of antigens, haptens, protein A or G, neutravidin, avidin, streptavidin, captavidin, antibodies, and complexes thereof.

28. An assay device as defined in claim 23, wherein said capture reagents at said scavenging zone and said detection zone are substantially identical.

29. An assay device as defined in claim 23, wherein the assay device is configured such that the analyte contacts said scavenging zone prior to contacting said conjugated detection probes.

30. An assay device as defined in claim 23, wherein the assay device comprises a sampling pad that defines said scavenging zone.

31. An assay device as defined in claim 30, wherein the assay device further comprises a conjugate pad located downstream from said sampling pad, wherein said conjugated detection probes are applied to said conjugate pad.

32. An assay device as defined in claim 23, wherein the assay device further defines a calibration zone within which a capture reagent is immobilized that is configured to bind to said detection probes or calibration probes, said calibration zone being configured to generate a calibration signal.

33. An assay device as defined in claim 32, wherein the quantity of the

analyte within the test sample in excess of said predefined base quantity is proportional to the intensity of the detection signal calibrated by the intensity of the calibration signal.

34. An assay device as defined in claim 23, wherein said detection probes
5 comprise a substance selected from the group consisting of chromogens, catalysts, luminescent compounds, radioactive compounds, direct visual labels, liposomes, and combinations thereof.

35. An assay device as defined in claim 23, wherein said capture reagent is immobilized within said scavenging zone.

10 36. An assay device as defined in claim 23, wherein said detection zone is located downstream from said scavenging zone.